UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

September 7, 1990

Holly Michaels Fisher
Director, Government Affairs and Health Policy
New York County Medical Society
40 West 57th Street
New York, NY 10019

Dear Ms. Fisher:

Thank you for your letters of April 3 and June 4, 1990, in regard to the Part 259 regulations for medical waste. As noted in your letter, physicians may practice health-care activities independently, in a group practice with no legal obligations, or in a group practice which is a legal entity.

The Part 259 regulations define a generator as any person, by site, whose act or process produces regulated medical waste (RMW) as defined in Section 259.30(a), or whose act first causes a RMW to become subject to regulation. These regulations also define "person" as "an individual, trust, firm, joint stock company, corporation (including a government corporation), partnership, association, State, municipality, commission, political subdivision of a State, any interstate body, or any department, agency or instrumentality of the United States." In cases where more than one "person" (e.g., doctors with separate medical practices) is providing services in the same examining room, each individual business entity is a separate generator. Thus, each person who generates RMW is subject to the requirements of Subpart E and Subpart F for management of RMW.

The preamble to the Part 259 regulations (54 <u>FR</u> 12349) discusses the disposal of small quantities of RMW from small individual generators. This is further discussed in the Question and Answer document enclosed (See Questions #46-49).

Generators of less than 50 pounds of RMW per month are given certain exemptions (e.g., the requirement to use a transporter who has notified, the requirement to use the tracking form, and the requirements of Subpart H) as noted in Section 259.51. However, the generator is still subject to all the requirements of Subpart E for pretransport of RMW which include appropriate segregation, packaging, storage, labeling and marking. Additionally, Section 259.51(a)(3) requires the generator to compile a shipment log and maintain records as required in Section 259.54(b)(2). However, nothing in the regulations preclude commingling of RMW provided that the generator can comply with the requirements of Subpart E and Subpart F for recordkeeping.

As you are aware, no generator can transfer its liability for the waste stream it is generating as a consequence of providing medical services. As discussed in the May 11, 1990 meeting, legal

corporations, by site, are viewed as one generator under the Part 259 regulations. Independent physicians who share examining rooms would be considered multiple generators, and each is liable for his or her own RMW.

If, however, independent physicians choose to commingle the RMW generated during the provision of medical care into one waste stream, all the generators could be held jointly and severally liable for civil and criminal violations of Part 259. We therefore do not recommend commingling RMW from more than one generator.

If you have further questions or require additional information please contact Mary Greene, at 202-475-7736.

Sincerely,

David Bussard, Director Characterization and Assessment

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